



Food and Drug Administration  
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Silver Spring, MD 20993-0002

GE Hualun Medical Systems Co., Ltd.  
Kenny Ma  
Regulatory Affairs Manager – X ray  
No.1, Yong Chang North Road  
Economic & Technology Development Zone  
Beijing, 100176  
CHINA

January 26, 2016

Re: K143270

Trade/Device Name: Optima XR646  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Station X-ray System  
Regulatory Class: Class II  
Product Code: KPR, MQB  
Dated (February 3, 2015):  
Received (February 5, 2015):

Dear Kenny Ma:

This letter corrects our substantially equivalent letter of February 3, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert Ochs".

Robert Ochs, Ph.D.

Director

Division of Radiological Health

Office of *In Vitro* Diagnostics and Radiological Health

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K143270

Device Name

Optima XR646

Indications for Use (Describe)

The Optima XR646 is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and is intended for use in all routine radiography exams.

The device is not intended for mammographic applications.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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### 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	October 29, 2014
Submitter:	GE Healthcare, (GE HUALUN MEDICAL SYSTEMS CO. Ltd) No.1 Yong Chang North Road, Beijing Economic Technological Development Zone BEIJING 100176 CHINA
Primary Contact Person:	Kenny Ma Regulatory Affairs Manager GE Healthcare, (GE HUALUN MEDICAL SYSTEMS CO. Ltd) Office: +8610 59347159 eFax: +8610 67882574 Email: Kenny.Ma@ge.com
Secondary Contact Person:	Christopher Paulik RA Leader - Product GE Healthcare, (GE Medical Systems, LLC) +1 262 548 2010 Email: Christopher.A.Paulik@ge.com
Device Trade Name:	Optima XR646
Common/Usual Name:	Digital Radiographic X-Ray System
Classification Names: Product Code:	Stationary X-Ray System (21CFR § 892.1680), solid state x-ray imager (21CFR § 892.1680) KPR, MQB
Predicate Device(s):	Stationary X-Ray System, MODEL: Discovery XR656 (K132261) and Revolution XR/d with Image Pasting (K050704)
Device Description:	The Optima XR646 remains a radiographic X-ray system capable of generating radiographic images of human anatomy.  The Optima XR646 is designed to handle radiographic applications using GE's flat-panel wireless digital detector. The digital detector is comprised of amorphous silicon and cesium iodide scintillator. The resulting digital image can be sent through a DICOM network for applications such as



	<p>printing, viewing and storage.</p> <p>The Optima XR646 Digital Radiographic Imaging system consists of a WallStand, elevating table, overhead Tube support, X-ray tube, collimator, system controller, X-ray generator, and wireless or tethered digital detector. Various configurations such as Table only, WallStand only, or OTS only are available to meet customer radiographic requirements.</p>
Intended Use:	General Purpose Digital Radiographic Imaging System
Indication for Use:	<p>The Optima XR646 is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and is intended for use in all routine radiography exams.</p> <p>The device is not intended for mammographic applications.</p>
Technology:	The Optima XR646 employs the same fundamental scientific technology as its predicate device.
Determination of Substantial Equivalence:	<p>Summary of Non-Clinical Tests:</p> <p>The Optima XR646 is based on the software and Hardware platform of the predicate device. It was designed and is manufactured under GE's quality system that meets the Quality System Regulations of 21 CFR 820 and ISO 13485.</p> <p>Optima XR646 is certified to comply with the X-ray requirements of 21 CFR Subchapter J – Radiological Health, as well as safety requirements of IEC 60601-1 and associated collateral and particular standards.</p> <p>The Optima XR646 and its applications comply with voluntary standards. The following quality assurance measures were applied to the development of the system:</p> <ul style="list-style-type: none"> <li>▪ Risk Analysis</li> <li>▪ Requirements Reviews</li> <li>▪ Design Reviews</li> <li>▪ Testing on unit level (Module verification)</li> <li>▪ Integration testing (System verification)</li> <li>▪ Performance testing (Verification)</li> </ul>



	<ul style="list-style-type: none"> <li>▪ Safety testing (Verification)</li> <li>▪ Simulated use testing (Validation)</li> </ul> <p>Minor obsolescence and feature changes have occurred in the evolution of the device for which a 510(k) was not required based on evaluation using the FDA “Deciding When to Submit a 510(k) for a change to an Existing Device”. These include changes in operator display and the reduction of option in overhead rails. The changes that precipitated this 510(k) submission were the reduction in auto positioning axes of the Overhead Tube Support that resulted in a change in the sequence of acquisitions for the Image Pasting feature.</p> <p>The Image Pasting feature change does not affect the functional equivalence of the product today. These differences do not raise new issues of safety and effectiveness. The Overhead Tube Support hardware change and the Overhead Tube Support movement control software change for Image Pasting function were verified and validated through bench testing. All the design inputs requirements were successfully tested for Optima XR646 with Image Pasting and meet the design specifications and user requirements. This Verification and Validation bench testing demonstrated that no adverse effects have been introduced by the changes. The control mechanism, operating principle, energy type and Intended use have not changed. The indication for use is slightly modified to reflect the removal of the VolumeRad feature from this version of the product also due to the reduction of auto positioning axes on the Overhead Tube Support.</p> <p>Based on the successful verification, validation, and bench testing and the above comparison, GE Healthcare believes that the Optima XR646 is as safe and effective and performs in a substantially equivalent manner to the predicate device.</p> <p>Summary of Clinical Tests: The subject of this premarket submission, Optima XR646, did not require clinical studies to support substantial equivalence. All changes were verified and validated during bench testing and did not reveal any new questions of safety and effectiveness.</p>
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**GE Healthcare**  
510(k) Premarket Notification Submission



Conclusion:	GE Healthcare considers the Optima XR646 to be as safe and effective, and performance is substantially equivalent to the predicate device.
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